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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,050	02/09/2004	Yu-Chan Chao	08919-103001 / 13A-900919	8997
26161	7590	09/26/2005	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			GUZO, DAVID	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/775,050

Applicant(s)

CHAO, YU-CHAN

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 7-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/18/04</u> . | 6) <input type="checkbox"/> Other: _____  |

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### **Detailed Action**

#### **Election/Restriction**

Applicant's election without traverse of Group I, Claims 1-6 in the reply filed on 8/23/05 is acknowledged.

Claims 7-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/23/05.

#### **35 USC 101 Rejections**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-2 read on a baculovirus that infects host cells without lyzing the cell. Baculoviruses can infect mammalian cells without lyzing the cells (See Carbonell et al., J. Virol., 1985, Vol. 56, No. 1, pp. 153-160, specifically page 153, left column) and baculoviruses which establish persistent infections in insect cells without apparently causing cell lysis have also been identified (See Hughes et al., J. Gen. Virol., 1997, Vol. 78, pp. 1801-1085). Since the claimed baculovirus is not recited as purified or recombinant or isolated, it reads on a naturally occurring baculovirus.

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### 35 USC 102 Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al.

Applicant claims a baculovirus that infects host cells (which can be insect cells) wherein said baculovirus comprises an exogenous nucleic acid sequence encoding a polypeptide containing a fluorophore and a method of expressing a polypeptide in a host cell, comprising infecting the host cell with said baculovirus. Applicant defines an example of a fluorophore as any of the naturally fluorescent amino acids; specifically, applicants indicate that a fluorophore can be "...a single fluorescent amino acid residue (e.g., tryptophan, lysine, cystine, or their fluorescent derivatives)" (p. 2 of the instant specification). Therefore, any polypeptide sequence containing a tryptophan, lysine, cystine, etc. will be considered a polypeptide containing a fluorophore. It is noted that the "non-lytic" baculovirus mutants disclosed by applicant are apparently not truly 100% non-lytic in host cells but can best be characterized as eliciting a lower level of cell lysis than elicited by infection with wild type baculoviruses. However, the baculoviruses disclosed by applicant can infect some cells in a given permissive insect cell culture without lyzing the cells.

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Lee et al. (cited by applicants, J. Virol., 1998, Vol. 72, No. 11, pp. 9157-9165, see whole article, particularly the Abstract, first four paragraphs of the "Results" section on p. 9158, Figs. 3-4) recites a baculovirus (a p35 gene deleted *Autographa californica* nuclear polyhedrosis virus, AcMNPV) which is capable of establishing a persistent (or latent) infection in insect cells which does not involve cell lysis of the persistently infected cells. The mutant baculoviruses disclosed by Lee et al. comprise a *lacZ* gene which possesses a fluorophore (i.e. a tryptophan or lysine residue) and is expressed in infected host cells. Lee et al. therefore teaches the claimed invention.

Claims 1-4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Carbonell et al.

Applicant's invention is as described above.

Carbonell et al. (J. Virol., 1985, Vol. 56, No. 1, pp. 153-160, see whole article, particularly the Abstract, pp. 156-157) recites recombinant baculoviruses which can infect mammalian cells or non-permissive insect cells (i.e. *Drosophila* cells) without lyzing said cells and wherein the baculoviruses comprise a exogenous gene encoding CAT wherein the CAT gene product comprises a fluorophore (such as a tryptophan or a lysine residue, etc.). The infected host cells express the CAT gene product after infection by the baculovirus. Carbonell et al. therefore teaches the claimed invention.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Juang et al.

Applicant's invention is as described above. Additionally, in claim 5, applicant claims the fluorophore as being a polypeptide containing ECFP, EYFP, EGFP or DsRed. The examiner is interpreting the claims reciting a polypeptide containing a fluorophore such as EGFP or DsRed, etc. as reading on EGFP or DsRed, etc. because a polypeptide containing EGFP, for example, can read on EGFP.

Juang et al. (US 2003/0022377, published 1/30/2003, filed 1/16/2002, see whole document, particularly paragraphs [0040], [0042], [0043], [0060], Claims 1, 12 and 13) teach use of sequences encoding the fluorophores EGFP, ECFP, EYFP and DsRed as markers for infection of host cells by the recombinant baculoviruses carrying the sequences encoding said markers. The recited baculoviruses are used to infect non-permissive mammalian and insect cells where the baculoviruses do not lyse the cells. Juang et al. therefore teaches the claimed invention.

### **35 USC 103(a) Rejections**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. in view of Davis et al.

Applicant's invention is as described above. Additionally, in claim 5, applicant claims the fluorophore as being a polypeptide containing ECFP, EYFP, EGFP or DsRed. This rejection is applied based upon a reading of claim 5 as reciting a fusion protein comprising one of the recited fluorophores.

Lee et al. is as described above. Lee et al. recites the potential use of the baculoviruses capable of establishing persistent infections in insect cells to produce polypeptides of interest in cells. Lee et al. does not teach use of baculoviruses encoding polypeptides containing a fluorophores such as ECFP, EYFP, EGFP or DsRed.

Davis et al. (US 2002/0115157, published 8/22/2002, filed 1/11/2002, see whole document, particularly paragraphs [0035], [0041], [0065], [0068]-[0071], [0250]-[0253]) recites recombinant baculoviruses encoding fusion polypeptides comprising a H2Ld polypeptide fused to a DsRed sequence.

The ordinary skilled artisan, seeking to choose a marker gene for use in determining what cells are infected and capable of expressing the recombinant

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protein of interest, would have been motivated to choose the DsRed marker because Davis et al. teaches that use of DsRed as an extracellular label provides excellent results in labeling proteins of interest in cells infected with recombinant baculoviruses comprising a sequence encoding DsRed fused to a protein of interest. It would have been obvious for the ordinary skilled artisan to choose the DsRed fluorophore as a marker in the baculoviruses described by Lee et al. because Davis et al. teaches that it is an excellent marker for detection of extracellular proteins when fused to said proteins. Given the teachings of the cited prior art and the level of skill of the ordinary skilled artisan at the time of applicant's invention, it must be considered that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo  
September 13, 2005

  
DAVID GUZO  
PRIMARY EXAMINER